RESOLUTION

2nd International Conference

«Quality Information for Quality Use of Medicines – QiQUM 2010»

Kazan, 15-16 October 2010

With joint efforts of co-organisers (listed in appendix) the second International conference "Quality information for quality use of medicines – QiQUM 2010" was held in Kazan, on the 15-16th of October 2010 (Information letter of the Ministry of Health and Social Development of the Russian Federation, dated 9th of August 2010, № 25-3/10/2-6802).

The principal aim and distinguishing characteristic was exclusion of pharmaceutical industry from participation to avoid its influence on formulating conference objectives, contents, invited speakers, programme development, information assessment and bringing together the results of the conference.

A Total of 414 specialists from 9 countries (Australia, Canada, India, Kazakhstan, Kyrgyzstan, Moldova, New Zealand, Switzerland and the USA), 20 regions of the Russian Federation, representatives of the World Health Organisation and the leading specialists from within and outside the Russian Federation – all from a professional international community – participated in the Conference and voted unanimously in favour of this resolution.

The scientific programme included plenary sessions, symposia, poster presentations, and a young scientist award competition.

The Conference noted

Progress in Russian medicines policy, namely: establishment of pharmacovigilance services; assessment of medicine information needs of health care providers; organization of a medicine price monitoring system; introduction of original domestically developed medicines; and first steps to develop and promote a national essential medicines list --developed in light of the WHO Model List of Essential

Medicines,

The Conference discussed

The diverse methods of drug promotion, used by the pharmaceutical industry, that violate ethical standards and contradict or subvert the mission of health systems and knowledge generation, including clinical trials.

The Conference recognized

The problems of the professional medical and pharmaceutical community, and even society as a whole, being misled by unethical drug promotion.

The urgent need for development, dissemination and implementation of independent evidence-based medicine information, as well as State-provided and Government-supported measures to counteract unethical drug promotion in all of its traditional, disguised and rapidly developing forms.

The Conference formulated the following priority areas for improving domestic medicine policy and health system needs:

- Full-fledged implementation of the WHO Essential Medicines Concept (WHO Essential Medicines List – Model Instrument, Model Product, and Model Process) aimed at effective formulary regulation of medicine use, being the most efficient strategy for providing equal access to Essential medicines, rational use of medicines, and fulfilment of the constitutional right to health.

- Planning and allocation of adequate financial and administrative support to strengthen the scientific community and provide science-based independent selection of health technologies and interventions to promote quality (rational) use of medicines both in public and private sectors.

- Further development of clinical pharmacology as the central component of pharmaceutical policy implementation in health systems; increasing the role of clinical pharmacology as a clinical, educational, and scientific discipline uniquely equipped with the needed level of expertise for development and dissemination of

independent drug information to ensure quality performance of physicians, pharmacists and nursing staff; hospitals and out-patient clinics require the input of clinical pharmacologists, and accordingly steps need to be taken to ensure the establishment and adequate staffing of clinical pharmacology posts.

- Indispensable involvement of clinical pharmacologists in development of various medicine lists and clinical guidelines for all levels of health care.

- Introduction of innovative technologies of development of independent medicines information and its delivery to professional medical and pharmaceutical community and society as a whole. Wide dissemination and use of an independent drug reference guide “Big Reference Medicines Guide”. Initiation of a Russian Independent Drug Bulletin.

- Development and approval of mandatory continuing educational programs on clinical pharmacology and principles of evidence-based medicine, rational (quality) use of medicines and modern information technologies for all health professionals including pharmacists. Implementation and inclusion of these programs in certification of specialists of all clinical disciplines. Continuing education of physicians and pharmacists in clinical pharmacology and rational use of medicines on regular basis as a part of certification requirement.

- Development and maximal assistance to community education programs on rational use of medicines. Independence of educational programs from the pharmaceutical industry needs to be ensured.

- Development of legislative measures to prohibit the dissemination of inaccurate medicine information, including unethical advertising practices of the pharmaceutical industry and its representatives. Development and further improvement of the existing normative and legislative bases, providing conformity with the WHO Ethical Criteria on medicinal drug promotion.

- Establishment of an independent expert body to monitor drug advertising and other forms of promotion. Development and implementation of mechanisms fund such an expert body, and to ensure its continuing development and effectiveness.

- Monitoring and control by independent experts of physicians' conferences and public speeches on the issues of informational content, scientific evidence base, completeness of data presentation, including adverse reactions data, in conformity with the WHO Ethical Criteria.

- Delivery to the medical professional community and to the society of official information on approved instructions on drug use, and determination of the legal status of the "Typical clinical pharmacological article" of the State Registry of the Russian Federation.

- Open access to all clinical trial data, including raw data from case report forms, and adverse drug reaction reports should be required and made publicly available to regulators, academics, the public, media and competitors through open access sources; tightening the regulatory requirements for competitor drug trials with existing drugs at their recognized safe and effective treatment levels, not just placebo drug trials.

- Improvement and development of a legislative base for conducting research involving human beings on health technologies including medicines to ensure the constitutional right to health and development of needed interventions, in contrast to the current practice of clinical trials as disguised drug promotion.

- Further development of a domestic pharmaceutical cluster following the original domestic scenario pursuing provision of priority health needs of citizens with essential medicines, avoiding repetition of mistakes of western multinational pharmaceutical companies (big Pharma).

- Further development of effective medicine surveillance services, including responsible and enforced pharmacovigilance in clinical trials of new pharmaceuticals: accurate reporting of adverse drug reactions must be strictly enforced and their unbiased analysis appropriately promulgated.

- Promotion of healthy lifestyles, in order to counteract smoking, excessive use of alcohol in society, and unwarranted medicine use.

The Conference decided:

1. To address an appeal to the Ministry of Health and Social Development of the Russian Federation, to the Ministry of Education and Science of the Russian Federation and to the Federal Service on Surveillance in Healthcare and Social Development (Roszdravnadzor) on adoption of these recommendations to practical implementation.

2. To appeal to the Ministry of Health and Social Development with the aim of strengthening and expanding clinical pharmacology services to consider the possibility of training new specialists on the basis of primary higher medical education specialty - “general medicine’, “pediatrics” and “general practice (family medicine)” regardless of further clinical specialization field. This is needed to provide retraining in clinical pharmacology for physicians specializing in narrow clinical fields, so that they can be employed as clinical pharmacologists in specialized health facilities (e.g. infectious disease, oncology, etc.)

Appendix

The list of Conference organizers (Russian alphabetical order)

Eurasian Academy of Medical Sciences,

GEOTAR publishing group,

Institute of Organic and Physical Chemistry named after A.E. Arbuzov of the Kazan

Centre of Russian Academy of Sciences,

Kazan State Medical Academy,

Kazan State Medical University,

Kazan State Technology University,

Ministry of Health of the Republic of Tatarstan,

Russian Scientific Society of Pharmacologists,

Tatneftechiminvest-holding,

Federal Service on Surveillance in Healthcare and Social Development, Tatarstan

Administration.

With financial support from the Government of the Republic of Tatarstan (Russian

Federation).